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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,689	12/08/2003	Todd K. Whitehurst	AB-311U	5724
23845	7590	06/22/2006	EXAMINER BERTRAM, ERIC D	
ADVANCED BIONICS CORPORATION 25129 RYE CANYON ROAD VALENCIA, CA 91355			ART UNIT 3766	PAPER NUMBER

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/730,689	Applicant(s) WHITEHURST ET AL.	
	Examiner Eric D. Bertram	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/10/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 8/10/2004 was filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4-9, 11 and 13-17 of copending Application No. 10/731,551 in view of Rise (US 5,824,021). The copending application discloses the basic method of implanting a stimulator near nerves in order to treat angina of a patient. The copending application does not specifically

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disclose implanting the stimulator within the spinal column in order to stimulate nerves of the patient. Attention is directed to the secondary reference of Rise, which teaches implanting a stimulator wholly with the spinal column in order to stimulate nerves for the treatment of angina (see figure 2 and Col. 2, lines 19-40). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the copending application by implanting a stimulator in the spinal column as taught by Rise in order to specifically stimulate nerves for the treatment of angina (Col. 1, lines 29-32).

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over King (US 6,058,331) in view of Dooley et al. (Modification of Blood flow to the extremities by electrical stimulation of the nervous system, hereinafter Dooley) and further in view of Schulman et al. (US 5,193,540, hereinafter Schulman). King discloses a method for treating a patient with peripheral vascular disease (PVD) and angina (i.e. ischemia of the heart). King describes implanting a stimulator, comprising lead 18 and signal generator 14, with at least one electrode within the spinal column of a patient in order to stimulate tissues that influence blood circulation (Col. 5, lines 2-30). Operating power is delivered to the stimulator by signal generator 14, which also receives stimulation parameters transmitted from external component 20 (Col. 4, lines 45-51). The pulse generator then generates stimulation pulses in accordance with the received parameters and delivers the pulses via the lead to the tissues that influence blood circulation. King discloses that the tissue may be a peripheral nerve from the spinal cord (Col. 5, line 1), which includes the spinal roots. However, since King does not

specifically disclose the stimulation of the spinal roots, attention is directed to the secondary reference of Dooley, which discloses the electrical stimulation of the peripheral nerves, and specifically the spinal roots, in order to improve blood flow to different parts of the body. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the method King by specifically stimulating the spinal roots as taught by Dooley, since Dooley discloses that patients with spinal root stimulation had significant arterial dilation in the extremities.

8. King, as described above, discloses the applicant's basic invention with the exception of using a stimulator that is entirely implantable within the spinal column of a patient. Attention is directed to the reference of Schulman, which discloses a miniature implantable stimulator (see figure 4). The stimulator is of such a size and shape (2mm x 10mm) that it is suitable for placement entirely within the spinal column of a patient by using a hypodermic needle (Col. 3, lines 53-68). Once the stimulator is implanted near the spinal roots, as taught by King and Dooley above, operating power and stimulation parameters are provided to the stimulator using transcutaneous transmission with external appliance 6, as shown in figure 2 (Col. 4, lines 36-51). The stimulator then generates pulses in accordance with the received parameters and delivers the pulses to the adjacent tissue by electrodes 14 and 15 (Col. 4, line 61-Col. 5, line 10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to substitute the stimulator of Schulman for the stimulator system of King, since they perform the same functions, and the stimulator of Schulman is less invasive and thus safer for use in the patient.

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9. Regarding claims 2, 3, 13 and 14, King discloses stimulating the lumbar area for treatment of PVD in a lower limb and stimulating the cervical area for treatment of PVD in an upper limb in a patient (Col. 5, lines 15-30).

10. Regarding claims 7-11 and 18-20, King discloses using a sensor 30 for monitoring the physical condition of the patient (Col. 5, lines 63-66). The sensed condition is then sent to the external component 20, which processes the signal from the sensor to adjust the stimulation parameters (Col. 4, lines 48-51). Alternatively, the sensor may send the signal directly to the stimulator, and the stimulator may internally adjust the stimulation parameters (Col. 6, lines 6-18).

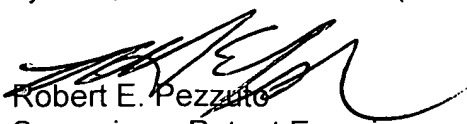
11. Claims 5, 6, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over King in view of Dooley and Schulman and further in view of Rise (US 5,824,021). King, as described and modified above, discloses the applicant's basic invention, including stimulating the patient's spinal roots in order to increase blood circulation to organs of the body experiencing ischemia, which would include angina. However, since King never specifically discloses the treatment of angina, attention is directed to the reference of Rise, which discloses delivering stimulation pulses to the thoracic area of the vertebrae as a treatment for angina (Col. 2, lines 27-29). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the method King by specifically stimulating the thoracic area of the vertebrae as treatment for angina as taught by Rise since this area will specifically increase coronary blood circulation in a patient (Col. 1, lines 29-32).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday and every other Friday from 9-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

Eric D. Bertram
Examiner
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EDB